Setial Number: 10/048072 Filing Date: Japuary 25, 2002 Title: Immunotherapy I HIV Infected Persons Using Vaccines After Multi-Drug Treatment



In the Claims

(Currently Amended) A method of stimulating a an efficient HIV1-specific CD8+ 1. response in a human infected with an HIV retrovirus said method comprising:

administering to the human, a nucleic acid-based recombinant viral vaccine, which enters the cells of the human and intracellularly produces HIV specific peptides for presentation on the cell's MHC class I molecules,

where said peptides are presented in an amount sufficient to stimulate a protective CD8+ HIV structural antigen response, and

where said human

- i. has a viral load of less than 10,000 viral copies per ml of plasma and a CD4⁺ cell count of above 500 cells/ml, and
- ii. has been treated with one or more anti-viral agents, which contributed to a lower viral copy and higher CD4⁺ cell count than before treatment

where said HIV specific peptides comprise HIV gag, gp120, nef or pol peptides.

- (Previously Presented) A method of claim 1 wherein the human has been treated with 2. anti-viral agents, which resulted in the human having a viral load of less than 1,000 viral copies per ml of blood serum and a CD4⁺ cell count of above 500 cells/ml.
- (Original) A method of claim 2 wherein the anti-viral agents comprise a combination of 3. protease inhibitors and inhibitors of reverse transcriptase.
- (Withdrawn) A method of claim 1 wherein the vaccine is a DNA based vaccine. 4.
- (Currently Amended) A method of claim 1 wherein the nucleic acid-based recombinant 5. viral vaccine is delivered by an attenuated recombinant virus.
- (Previously Presented) A method of claim 5 wherein the attenuated recombinant virus 6. comprises a pox virus.

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7. (Previously Presented) A method of claim 6 wherein the attenuated recombinant pox virus comprises NYVAC or ALVAC.

- 8. (Previously Presented) A method of claim 6 wherein the recombinant pox virus comprises MVA.
- 9. (Original) A method of claim 1 where the vaccine is administered a second time.
- 10. (Previously Presented) A method of claim 1 wherein the HIV specific peptides are structural viral peptides.
- 11. (Canceled).
- 12. (Original) A method of claim 1 wherein the vaccine further comprises an adjuvant.
- 13. (Original) A method of claim 1 further comprising administering interleukin 2 or CD40 ligand in an amount sufficient to potentiate the CD8⁺ response.
- 14. (Previously Presented) A method of claim 1 where the human has been infected with HIV and has demonstrated repeated and sustained proliferative T-cell responses to gp120 envelope protein.
- 15. (Previously Presented) A method of claim 14 where the human has demonstrated repeated and sustained proliferative T-cell responses to p24 gag antigen.
- 16. (Previously Presented) A method of claim 1 where the human is infected with HIV and is further tested by a skin test for a hypersensitive response to p24 gag antigen.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111 Serial Number: 10/048072

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(Previously Presented) A method of claim 1 where the human is infected with HIV and is 17. further tested by a skin test for a hypersensitive response to gp120 envelope antigen.